Research into the shorter and longer term effects of two low-intensity exercise programs in people with type 2 diabetes mellitus (T2DM)

Published: 09-04-2024
Last updated: 01-05-2024

see also aboveThe aim of the project is to investigate the effects of an accessible 20- and 50-week walking intervention for people with diabetes. This examines the level of physical activity, quality of life, patient activation, diabetes self-...

Ethical review	Approved WMO
Status	Pending
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Interventional

Summary

ID

NL-OMON56715

Source
ToetsingOnline

Brief title
effects of two low-intensity exercise programs in people with T2DM

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
type 2 diabetes mellitus; adult type diabetes

Research involving
Human

Sponsors and support

Primary sponsor: Bas van de Goor Foundation

Source(s) of monetary or material Support: Diabetesfonds Nederland; Bas van de Goor Foundation;Papendal; Stichting onderzoek Chronische Ziekten;Zwolle

Intervention

Keyword: 20 or 50 weeks intervention, structured walking program, type 2 diabetes mellitus

Outcome measures

Primary outcome

Research is being conducted on the following outcome measures

Questionnaires for all participants (A+B):

• General questions

• Quality of life: WHO-5 and EQ5D5L

• Patient activation: PAM-13

• Diabetes management: SDSCA

In a subgroup of 60 participants with T2DM (to which this METC application

relates; B):

• HbA1c

• Medication use

• Number of contact moments in the general practice in the six months before

the measurement moment

• Number of steps using Garmin VivoFit 4

• Glucose monitoring using Abbott FreeStyle Libre 2 (see also

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9564842/pdf/ijerph-19-12296.pdf)

Primary outcome measures for the 60 participants in the more intensive study

(B) are the possible changes:

- in number of steps

- in glucose regulation

- in perceived changes in well-being and quality of life.

Secondary outcome

The other outcome measures mentioned are seen as secondary outcome measures

(see above)

Study description

Background summary

The National Diabetes Challenge (NDC) has already proven to be able to mobilize the vulnerable group of people with diabetes, who often have a lower socio-economic position. Previous research into the effects of the NDC has shown that the NDC contributes to an improvement in quality of life, with a lower BMI, waist circumference, blood pressure, medication use and HbA1c. More evidence is needed that the NDC delivers (health) benefits, especially when it comes to longer-term effects.
With the arrival of the GALA, control over prevention has fallen to the municipalities. When this is implemented through the NDC, municipalities want to see that this results in a better quality of life and more self-reliance among vulnerable participants. The results of the research project will be used in accountability to the municipalities. (Co-)financing from municipalities is necessary to be able to offer the NDC structurally and on a larger scale throughout the Netherlands. The need for structural financing is growing, because referring participants then comes 'between the ears' of healthcare providers and can become part of their work. For exercise and wellness professionals, the NDC will then be included annually in the implementation plans and they can continue to expand and consolidate the local network and collaboration.
In addition, if the results are favorable, the research will contribute to recognition of the intervention by the Healthy Living Desk/RIVM, with the desire to move to the *Effective* level. This increases the chance of a conversation with other municipalities and assurance of the NDC. But it also keeps the options open to grow from recognition to a Combined Lifestyle

Intervention. Insurers and municipalities have jointly made agreements in the Integrated Care Agreement (IZA) and Regional Images whereby the chances of the NDC increase if there is good scientifically substantiated research on the impact of the challenge.

The most common outcome measures that participating parties and financiers have focus on the following main themes:
- Are there sufficient somatic changes, such as an increase in the number of steps per day, changes in weight, changes in blood pressure and changes in glucose regulation and medication use? We have been able to demonstrate these types of changes (reports available), although not all data has been published.
- Are there changes in mental and social factors that indicate an improvement in well-being, quality of life, self-efficacy in terms of feeling more responsible for the management of one's own diabetes? We have also studied that, but here too the results have not all been published.
- How long does the effect of the intervention last? In any case, we were able to see an effect up to and including a year and a half (unpublished data)
- Is this intervention cost-effective? Of course, that largely depends on how you define cost-effectiveness. If you look from a Social Return on Investment (SROI) perspective, every euro invested ultimately yields ¤ 4.55 (report available)

For research into these themes, research that has already been conducted is partly repeated, combining previously researched aspects, supplemented with linking data from participants to the CBS data and in-depth analysis (continuous glucose monitoring) with a subgroup of participants. For the most relevant outcomes, participants are followed for up to two years after the start of the intervention. Many of today's financiers want to know what the longer-term effects are. In addition, it provides the opportunity to see whether the DIB (50 weeks) is more effective than the NDC (20 weeks). The proposed plan, as described below, is based on this.

Study objective

see also above

The aim of the project is to investigate the effects of an accessible 20- and 50-week walking intervention for people with diabetes. This examines the level of physical activity, quality of life, patient activation, diabetes self-management, somatic health, medication use and glucose metabolism.

The research questions that are answered are:
• What is the effect of participation in the NDC and Diabetes in Movement on the level of physical activity, measured in the number of steps taken per day, in the period before the intervention, during the intervention, and 1 year and 2 years after the start of the intervention?
• What is the effect of participation in the NDC or Diabetes in Motion on

glucose regulation, comparing the baseline data with the data halfway and at the end of the intervention?
• What is the effect of participation in the National Diabetes Challenge and Diabetes in Motion on the quality of life and (diabetes) self-management, medication and weight 20 weeks, 1 year and 2 years after the start of the intervention?

Study design

This is a prospective cohort study among people with diabetes who participate in the NDC (20 weeks) or Diabetes in Motion (50 weeks) in 2024 with four measurement moments (T0 - T3). Participants will be followed for 2 years after the start of the intervention.
People that subscribed to one of the walking interventions are invited to participate in the study. All people who show interest in participation in either the NDC of the DiB will when they are enrolled for the challenges (estimate of expected participants in 2024 over 3,000 persons) receive a message to confirm their participation. In this confirmation message they will be asked whether they are interested in participation of the study as presented now. Those individuals who show interest will receive the subject information sheet of the study (*patient informatie brief*), and when they agree to participate included in the study (consent form) provided with more detailed information.

Intervention

All participants in the NDC 2024 will receive a digital invitation to participate in the study before the start of the 20-week walking intervention in April. This will take place in September for participants in Diabetes in Motion (50-week intervention). If participants have given permission to participate, they will be asked for permission to link with CBS data. Participants receive online questionnaires by email. These questions relate to quality of life, patient activation and diabetes management. These questionnaires are sent again after 20 weeks (T1), 1 year (T2) and 2 years (T3). This group is referred to as group A in the outcome measures.

In a subgroup of 60 participants (30 NDC, 30 DIB) with T2DM, the number of steps and blood glucose levels are also mapped. Prior to the intervention, they receive an activity tracker (Garmin VivoFit 4) to keep track of the daily number of steps. For three weeks, participants wear a glucose sensor (FreeStyle Libre 2), which measures the glucose concentration every minute. For the entire subgroup, the first contact will have to take place well before the start of the walking intervention, in order to also take baseline measurements of both glucose metabolism and exercise pattern. This group is referred to as group B in the outcome measures.

Study burden and risks

A number of efforts are required on the part of the participants, such as helping to make the generated data accessible (Vivofit and FSL2) and completing the questionnaires repeatedly.
There are no risks associated with any of these interventions, except for the very small chance that a subcutaneous vessel will be punctured when inserting the FSL2 probe.

Contacts

Public
Bas van de Goor Foundation

Papendal 7
Arnhem 6816VD
NL
Scientific
Bas van de Goor Foundation

Papendal 7
Arnhem 6816VD
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

The study population consists of people with T2DM who register for one of the

walking interventions in 2024: the national diabetes challenge (20 weeks) or Diabetes in Motion (50 weeks).

Exclusion criteria

In principle, anyone who considers him- or herselve capable of maintaining a walking intervention for a longer period of time can participate. The most important exclusion criterion is inability to maintain the walking intervention.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2024
Enrollment:	60
Type:	Anticipated

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	09-04-2024
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL86161.056.24